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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,686	07/25/2001	GALINA MIKHAILIVNA ERKHOVA	ERKHOV-1 PCT	2044

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EXAMINER	
CANELLA, KAREN A	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/673,686	ERKHOVA, GALINA MIKHAILIVNA	
	Examiner	Art Unit	
	Karen A. Canella	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 6-11 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 6-11 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 12 and 13 have been canceled. Claims 6-9 have been amended. Claims 6-11 are pending and under consideration.

The text of Title 35, U.S. Code not found in this action can be found in a prior action.

The rejection of claims 6-11 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is maintained for the following reasons of record. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention..

Claims 6-8 are drawn to a method of producing an antiserum that specifically binds to antigen-stimulated lymphocytes comprising performing a first immunization by immunizing a rat with a suspension of cells from a fetus pf the same genetic line as the animal being immunized; recovering the spleen cells from said first immunized animal and separating the lymphocytes therefore to obtain a lymphocyte suspension; performing a second immunization by administering the lymphocyte suspension to animals of the same genetic line as in the first immunization, recovering the antiserum; adding cells of whole organs of said animals to said antiserum to form a suspension, and separating the supernatant to recover antiserum that specifically binds antigen-stimulated lymphocytes. Claims 9-11 are drawn to the method of diagnosing a malignant tumor, comprising contacting the antiserum of claims 6-8 with a sample of tissue, blood or other physiological sample of a subject to be examined, and determining the presence of a malignant tumor by deviation of the test result from a control test.

35 U.S.C. first paragraph requires that one of skill in the art be able to make the anti-idiotypic anti-embryonic antiserum of the invention and use it in the claimed method without undue experimentation and with reasonable expectation of success.

Step v) of claim 6 requires that cell of "whole organs" be added to the anti-idiotypic anti-embryonic antiserum to form a suspension and that a supernatant should be allowed to separate from sediment, wherein the supernatant is the final product which specifically binds to the antigen-stimulated lymphocytes. Neither the specification nor the prior art provides teachings as

to what this step should accomplish, the kind of organs needed to make the suspension, or the amount of organs required to produce the anti-idiotypic anti-embryonic serum which would have the qualities necessary to carry out the methods of claims 9-11 with reasonable expectation of success. The anti-idiotypic anti-embryonic antiserum would be a polyclonal antiserum with reactivity to a population of fetal antigens. The specification has not provided teachings regarding the type of organs to be used in step v) or the amount of organs relative to the amount of the lymphocyte suspension. The specification has not provided an in vitro assay whereby one of skill in the art could determine the types of organs needed and the amount of organs relative to a lymphocyte suspension that would be necessary to produce an anti-idiotypic antiserum to carry out the methods of claims 9-11 with reasonable expectation of success. The specification has not provided theoretical teachings regarding the purpose of step v), so one of skill in the art could not envisage an in vitro test to determine the types of organs needed and the amount of organs relative to a lymphocyte suspension that would be necessary to produce an anti-idiotypic antiserum with the qualities necessary to carry out the methods of claims 9-11 with reasonable expectation of success. Given the lack of teachings in the specification regarding section v) of claim 6, one of skill in the art would be subject to undue experimentation without reasonable expectation of success in order to make and use the anti-idiotypic anti-embryonic antiserum of claim 6.

Applicant argues that the specification describes heterotypic antigen and that these exist in normal tissues in addition to being expressed in tumors Applicant argues that the specification indicates that kidney and liver should be used as the whole organs to remove antibodies against these heterospecific antigens. this has been considered but not found persuasive. The specification states on page 2, lines 3-7, that

There is a specific group of antigens, so called heterospecific antigens, existing. They could not be classified as heterologous to the organism, while besides tumors they exist in other normal tissues . Among heterospecfic antigens there is a renal antigen, which exists as a norm on the kidney and in the tumor of liver hepatoma.

However, there is no teachings as to the particular selection of these organs in the method of making the specific antiserum of claim 1. further, there is no teachings of the relative amounts

of the "whole organs" relative to the recovered antiserum that are necessary for the proper biding of the undesirable portion of the antiserum recovered from the rat in step iv. The specification has not provided an in vitro assay whereby one of skill in the art could determine the types of organs needed and the amount of organs relative to a lymphocyte suspension that would be necessary to produce an anti-idiotypic antiserum to carry out the methods of claims 9-11 with reasonable expectation of success. The specification has not provided theoretical teachings regarding the purpose of step v), so one of skill in the art could not envisage an in vitro test to determine the types of organs needed and the amount of organs relative to a lymphocyte suspension that would be necessary to produce an anti-idiotypic antiserum with the qualities necessary to carry out the methods of claims 9-11 with reasonable expectation of success. For these reasons one of skill in the art would be subject to undue experimentation in order to make and use the specific antiserum that specifically binds antigen-stimulated lymphocytes.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 11 am to 10 pm, except Wed, Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella, Ph.D.
8/8/2005

KAREN A. CANELLA PH.D
PRIMARY EXAMINER